

Date Issued November 2016

Issue Ortho Clinical Diagnostics (Ortho) is issuing this Urgent Product Correction Notification because we have received customer complaints and have confirmed the intermittent presence of marked haemolysis in Ortho Reagent Red Blood Cell (RRBC) products as well as Quality Control products containing red blood cells.

We have conducted an extensive investigation, and the root cause for the marked haemolysis, as illustrated below, has been identified as microbial contamination.



Affected Products The enclosed "List of Affected Red Blood Cell Products" indicates all product lots that Ortho has identified as potentially subject to microbial contamination.

Impact to Results If markedly haemolysed red cell products are used in testing, erroneous (false positive or false negative) results may be generated, which can potentially lead to patient harm. To date, Ortho has received no reports of erroneous patient/donor results due to this issue. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. As a reminder, the *Precaution* Section of the Instructions for Use for these products states:

"Do not use reagents if marked haemolysis or evidence of contamination is observed."

Resolution Corrective actions have been implemented and any RRBC product lots that expire after 2016-12-16 should not exhibit this haemolysis.

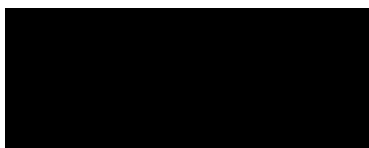
- Required Actions**
- Visually inspect all products prior to use; per the Instructions for Use, do not use red cell products if marked haemolysis or evidence of contamination is observed.
 - Contact the Ortho Care™ Technical Solutions Centre to report a product in which marked haemolysis is observed so that the product can be credited.
 - Complete and return the Confirmation of Receipt form by **9 November 2016**.

**Contact
Information**

Ortho would like to apologize for the inconvenience and the increased workload that this issue may have caused your laboratory.

We thank you and your staff for your patience and cooperation as we manage the resolution of this issue. If you have questions or require additional information, please contact the Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Sincerely,



Jon Wong

QA Manager

Enclosure:
List of Affected Red Blood Cell Products

List of Affected Red Blood Cell Products—International

Product Code	IFU Product Name	Lot Number	Expiration Date
719111	0.8% BioVue [®] Screen	BVS312	2016-11-01
		BVS313	2016-11-29
719202	Reagent Red Blood Cells 0.8% Affirmagen [®]	8A511	2016-09-13
		8A512	
		8A522 8A523	2016-10-11
		8A534	2016-11-08
		8A548	
719211	Reagent Red Blood Cells 0.8% AFFIRMAGEN [®] 3	83A289	2016-09-13
		83A290	2016-10-11
		83A291	2016-11-08
719212	Reagent Red Blood Cells 0.8% AFFIRMAGEN [®] 3	83A289	2016-09-13
		83A290	2016-10-11
		83A291	2016-11-08
719220	Affirmagen [®] 4	4A919	2016-09-13
		4A920	2016-09-27
		4A921	2016-10-25
719221	Reagent Red Blood Cells 0.8% Affirmagen [®] 4	84A311	2016-09-13
		84A312	2016-10-11
		84A313	2016-11-08
719310	Reagent Red Blood Cells (Pooled Cells)	A2627	2016-09-13
		A2629	2016-09-27
		A2630	2016-10-11
		A2632	2016-10-25
		A2634	2016-11-08
		A2635	2016-11-22
6901863	Selectogen [®] (10758750007318)	S926	2016-09-06
		S930	2016-09-20
		S933	2016-10-04
		S935	2016-10-18
		S937	2016-11-01
6901864	Surgiscreen [®]	3SS214	2016-09-06
		3SS228	2016-10-04
		3SS231	2016-10-18
		3SS241	2016-11-08

Product Code	IFU Product Name	Lot Number	Expiration Date
6901865	Resolve® Panel A	RA038	2016-09-13
		RA039	2016-09-27
		RA040	2016-10-11
		RA041	2016-10-25
		RA042	2016-11-08
		RA043	2016-11-22
6901866	Resolve® Panel B	RB451	2016-08-30
		RB452	2016-09-13
		RB453	2016-09-27
		RB454	2016-10-11
		RB455	2016-10-25
		RB456	2016-11-08
6901867	Resolve® Panel C Ficin Treated	RC450	2016-09-13
		RC451	2016-10-11
		RC452	2016-11-08
6901868	Ortho® Coombs Control	K356	2016-09-06
		K362	2016-10-04
		K365	2016-10-18
		K368	2016-11-01
		K374	2016-11-15
		4A925Z	2016-09-13
		4A926Z	2016-09-27
		4A927Z	2016-10-25
		4A928Z	2016-11-08
707930	Affirmagen®	A895Z	2016-09-13
		A896Z	
		A900Z	2016-09-27
		A901Z	
		A910Z	2016-10-25
		A911Z	
		A915Z	2016-11-08
		A916Z	
707940	Selectogen®	S926Z	2016-09-06
		S932Z	2016-09-27
		S935Z	2016-10-18
		S938Z	2016-11-08

Product Code	IFU Product Name	Lot Number	Expiration Date
707950	Surgiscreen®	3SS214Z	2016-09-06
		3SS216Z	2016-09-13
		3SS222Z	2016-09-27
		3SS225Z	2016-10-04
		3SS231Z	2016-10-18
		3SS238Z	2016-11-01
		3SS241Z	2016-11-08
719102	0.8% Surgiscreen®	8SS271	2016-09-06
		8SS272	
		8SS273	
		8SS274	
		8SS275	
		8SS276	2016-10-04
		8SS277	
		8SS278	
		8SS279	
		8SS280	
		8SS281	2016-11-01
		8SS282	
		8SS284	
		8SS285	
		8SS286	
719402	0.8% Resolve® Panel C System	8RC306	2016-10-04
		8RC307	2016-11-01
		8RC308	2016-11-29
719502	0.8% Resolve® Panel A	8RA329	2016-09-06
		8RA330	2016-10-04
		8RA331	2016-11-01
719522	0.8% Resolve® Panel B	8RB329	2016-09-06
		8RB330	2016-10-04
		8RB331	2016-11-01

Product Code	IFU Product Name	Lot Number	Expiration Date
719602	0.8% Selectogen®	8S893	2016-09-06
		8S894	2016-10-04
		8S896	2016-11-01

Japan Only			
Product Code	IFU Product Name	Lot Number	Expiration Date
7192870	Group O Cell	O400	2016-09-13
		O401	2016-09-27
		O402	2016-10-25
		O404	2016-11-08
7196771	3% Diego Cells	DIA202	2016-09-13
		DIA203	
		DIA204	
		DIA205	2016-10-04
		DIA206	
		DIA207	
		DIA209	2016-10-25
		DIA210	
		DIA211	
		DIA212	2016-11-15
		DIA213	
		DIA214	
7191041	Reagent Red Blood Cells Surgiscreen®	3SS212	2016-08-30
		3SS215	2016-09-06
		3SS217	2016-09-13
		3SS218	
		3SS219	
		3SS221	2016-09-20
		3SS226	2016-10-04
		3SS227	
		3SS229	2016-08-30
		3SS234	2016-10-25
		3SS236	
		3SS237	
		3SS239	2016-11-01
		3SS240	
		3SS245	2016-11-15
		3SS246	
		3SS247	

Japan Only			
Product Code	IFU Product Name	Lot Number	Expiration Date
7192041	Reagent Red Blood Cells (Pooled Cells) Affirmagen®	A897	2016-09-13
		A898	
		A902	2016-09-27
		A903	
		A906	2016-10-11
		A907	
		A908	
		A912	2016-10-25
		A913	
		A914	
		A918	2016-11-08
		A919	
		A920	2016-11-22
		A921	
		A922	
7198041	Reagent Red Blood Cells (Pooled Cells) Ortho® Coombs Control	K356	2016-09-06
		K357	
		K359	2016-09-20
		K360	
		K361	
		K362	2016-10-04
		K363	
		K364	
		K365	2016-10-18
		K366	
		K368	2016-11-01
		K369	
		K370	
		K372	2016-11-15
		K374	